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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,382	12/29/2004	Alain Sanson	263859U/SOX PCT	7625
22850	7590	08/21/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
GUPTA, ANISH				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
08/21/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/518,382

**Applicant(s)**

SANSON ET AL.

**Examiner**

ANISH GUPTA

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-11, 21-23 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11, 21-23 and 26-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18 2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5-11, 21-23, 26-28 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended from J represents amino acids to all the J variables defined by specific amino acids. Thus, now J26 is defined as Leu, Val or Ile, J64 as Phe, Leu or Met, etc. . . New claim defines all of the J variables with specific amino acids in each J variable position. This amendment to the claims constitutes new matter.

### **Lack of Literal Support**

The originally filed disclosure discloses J an natural amino aids, "in such a manner that at least 50% of them are polar residues chosen from Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn,

Pro, Ser, Thr, and Tyr (see page 11). Furthermore, the specification state that all J's can be chosen from Ala, Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Ile, Leu, Lys, Met, Orn, Phe, Pro, Ser, Thr, Trp, Tyr, and Val (see page 15 of the specification). However the specification does not specifically recite that J 26, for example, is only Leu, Val, Ile. There is no literal support for the specific J variables as claimed in claim 1 and new claim 30.

### **Lack of Inherent Support**

“While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” MPEP 2163. The originally filed disclosure does not provide either implicit or inherent support for the new limitations. There is no guidance within the specification that J variable have specific amino acid substitutions as now currently claimed. The specification generally teaches that J variables are surface amino acids or residues of this peptide when it is in the folded and active conformation. However this does not lead on of ordinary skill in the art to envision that J are very specific residues as currently claimed. The specification only describes the J's in a general manner without any specificity with respect specific amino acid at any given J position.

The specific example and species also do not provide any implicit or inherent support for the markush for the J variables as now claimed. The specification discloses fourteen specific amino acid sequences. These fourteen amino acid sequences do not adequately represent the variability of the claimed genus. For example, the claimed invention states that variable J74 can be Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, Tyr. However, the none of the examples have amino acids that contain a Cys, Lys, Pro or Orn, for example, in position J74. This is also true of other positions within the markush. Furthermore, the species do not provide support for all of the

differing combinations of the J variables. There are no species that have Orn in more than one J position. For that matter, there are no species that contain a single Orn residue in any position. Thus, the claims do provide implicit support for the new markush group.

### **New Grounds For Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 29, 30-33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims recite specific amino acid sequences that depend from claim 1. However, these sequences do not comply with the markush group of claim 1. For example, claim 1 states that J26 is selected from Leu, Val and Ile, thereby implying that J26 can only be Leu, Val or Ile. However, SEQ ID NO 11-14 all contain other amino acids than Leu, Val or Ile. SEQ ID NO 11-12 contains Glu, SEQ ID 13 contains a Gly and SEQ ID 14 contains a Met. This is also true of variable J64. SEQ ID 12 does not contain a Arg residue in position 37. Thus, read properly claim 4 does not properly depend on claim 1, since claim 4 contains sequences that do not comply with the Markush Group of claim 1. Applicants are requested to review all of the Sequences claimed to see if they comply with the amended claims.

Claim 30 states that peptide comprises "the following peptide sequence (PI) (SEQ ID NO:18):" and recites a large sequence. However, the sequence listing lists SEQ ID 18 as Gly-Cys-Gly-Ser. It is unclear how this tetrapeptide relates to the large sequence claimed in claim 30.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654